Response to “A paradigm shift in eye banking: how new models are challenging the status quo by Moshirfar et al”

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Dear editor

I thank Dr. Mannis for his reply to our perspective editorial concerning the Paradigm Shift in Eye Banking. As mentioned in our abstract the goal of this article is to create a platform to promote further discussions. There are indeed 14, not 11, paragraphs in this article and CorneaGen has been mentioned, not necessarily supported, in 11, not 6, of the paragraphs. This correction may seem petty, but the number of paragraphs is no way a reflection of a bias. I must start by stating that none of the authors in this manuscript has any financial interest in SightLife or CorneaGen, and we have never obtained cornea tissue from CorneaGen. I am the co-director of a local community Eye Bank and I do take my role quite seriously concerning this noble and important cause for our community. In another words, Dr. Mannis, I am on the same side with you concerning this dilemma.

You are accusing us of being biased in our editorial but fail to actually specify our biased comments. What comment was erroneous and biased in your opinion? As mentioned, we simply wanted to create a platform for both sides for further dialogue without adopting a reprimanding tone or trying to state if one side is more righteous than the other.

As mentioned in our introduction, we have been confronted with this dilemma ourselves and simply wanted to share our thoughts with other cornea surgeons. We tried to weigh the issues of innovation, philanthropy, and economies of scale against the matter of ethical and moral judgment. We emphasized in our introduction that there should be a balance between scientific advancement and ethical values. However, we cannot ignore the fact that SightLife consortium is gaining a large impressive foothold in the marketplace. The fact that increasing number of cornea surgeons is using SightLife services with a satisfaction rate approaching 100% should not be ignored. Instead, we need to learn how we can do things better as community eye banks in order to maintain our legacy.

My co-authors and I did mention that this paradigm shift will most likely impact other eye bank consortiums and that smaller eye banks have been forced to consolidate or fail. We did address that in this competition there has been an overture of salesmanship by CorneaGen that has subsequently alienated some cornea surgeons and eye banks and has raised the question if this is truly helpful to the industry of eye banking.

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We also mentioned how the presence of the Organ Procurement Organization (OPO), a certified agency by Centers of Medicare and Medicaid Services (CMS), has given legitimacy to the collaboration with SightLife. In the discussion of Venture Philanthropy, we raised the question of the fairness of monetizing a generously gifted cornea tissue. We addressed our concern that both CorneaGen and SightLife have identical mission statements and share 13 board members on their boards of medical directors and advisers. This alone can create doubt and ambiguity in the mind of cornea surgeons.

Thank you, Dr. Mannis, for reminding us that the World Health Organization (WHO) Principles of Transplantation and the Barcelona Principles for Eye Banking, endorsed by many eye bank organizations including the Eye Bank Association of America (EBAA), do not support the for-profit model. On the same note, we cannot ignore the fact that several independent legal firms scrutinized the same WHO, US-FDA, and EBAA regulations prior to formalizing the CorneaGen. They concluded that the business strategies of CorneaGen did not conflict with any of the regulations and principles, legitimizing CorneaGen's presence in the eye banking industry. Indeed, we did address in our editorial that regardless of the above mentioned legality of CorneaGen, ethical questions remain. We also raised the concern of what would happen if CorneaGen became a publicly traded company that would hold the responsibility to its shareholders to maximize revenues.

Dr. Mannis these concerns are not mere lip service to the critics. It shows our non-biased approach to this important issue. CorneaGen (a for-profit organization) partners with SightLife (a non-profit organization) for harvesting tissue. Whether or not the subsequent transfer of this tissue to CorneaGen is legal and ethical was beyond the scope of

our article. We simply laid issues for the readers to formulate their own opinion. Any *legal* issue should be resolved in a proper court of law. Any *ethical* issue should be resolved by an appropriate ethical review committee convened by eye bank directors, such as yourself, if they deem it necessary to challenge this new model.

In conclusion, I dispute that our editorial perspective is biased. We have no experience dealing with CorneaGen nor do we have any financial interest in CorneaGen. Instead, we depend on our local traditional eye bank with no ties to CorneaGen. Our interest lies only in starting an enlightened discourse on a new model of eye banking. Numerous hospitals and eye banks have partnered with CorneaGen and it is these entities that we hope would respond by writing about their experience with non-traditional eye banks.

If like us, you and your institution have not interacted with non-traditional eye banks, then while we are on the same side of the fence perhaps we should soon forge an alliance with other local eye banks to maintain our competitive autonomy in this market. The other choice is to allow a Venture Philanthropist flourish in the eye bank industry and we should stop complaining.

Dr. Mannis, just like you, I uphold a certain reputation in our professional community. After 23 years of cornea practice and 260 published scientific articles as corresponding author, my work has never been labeled as "a most unfortunate analysis, clearly not free of bias." Once again I would like to take this opportunity to thank you for your letter and I'm thrilled that it is creating a dialogue.

Disclosure

The author reports no conflicts of interest in this communication.

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